

Introduced by Senator Migden

January 31, 2007

An act to amend Sections 124977 and 125002 of the Health and Safety Code, relating to maternal and child health, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 164, as introduced, Migden. Prenatal screening.

Existing law imposes various responsibilities upon the State Department of Public Health and prenatal care providers with respect to prenatal care, screening, and counseling, and requires the department to administer a statewide program for prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing for genetic disorders and birth defects. Existing law establishes the Birth Defects Monitoring Program in the department's maternal, child and adolescent health program, and requires the Deputy Director for Maternal, Child, and Adolescent Health to maintain a system for the collection of prescribed information on birth defects. Existing law also provides for an increase in prenatal screening fees to support the program activities and specifies the steps for release of pregnancy blood samples for research purposes. Existing law requires that those fees be deposited in the continuously appropriated Genetic Testing Fund.

This bill would change the name of the Birth Defects Monitoring Program to the Birth Defects Monitoring and Biomedical Resources Program. The bill would require the department to also charge investigators, who are approved by the department to use pregnancy blood for research purposes, a fee for costs related to data linkage, storage, retrieval, processing, data entry, reinventory, and shipping of

pregnancy blood or its components, and related data management, as provided. The bill would require that the moneys collected from the prenatal fee increase and the usage and retrieval charge be deposited in the Birth Defects Monitoring and Biomedical Resources Program Fund, which the bill would create, and that would be continuously appropriated to support the activities of the program.

The bill would additionally require that the program develop blood collection and processing protocols, determine conditions and recommendations for the duration of blood storage, establish exclusion criteria for blood specimens, and institute safe and secure methods for the disposal of specimens, as determined by the program. The bill would require the department to store the pregnancy blood for research purposes, as prescribed, and analyze the costs of pregnancy blood storage, and annual data linkage and management, and to adjust the fee accordingly.

Vote: majority. Appropriation: yes. Fiscal committee: yes.
State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 124977 of the Health and Safety Code
2 is amended to read:
3 124977. (a) It is the intent of the Legislature that, unless
4 otherwise specified, the program carried out pursuant to this chapter
5 be fully supported from fees collected for services provided by the
6 program.
7 (b) (1) The department shall charge a fee to all payers for any
8 tests or activities performed pursuant to this chapter. The amount
9 of the fee shall be established by regulation and periodically
10 adjusted by the director in order to meet the costs of this chapter.
11 Notwithstanding any other provision of law, any fees charged for
12 prenatal screening and followup services provided to persons
13 enrolled in the Medi-Cal program, health care service plan
14 enrollees, or persons covered by health insurance policies, shall
15 be paid in full directly to the Genetic Disease Testing Fund, subject
16 to all terms and conditions of each enrollee's or insured's health
17 care service plan or insurance coverage, whichever is applicable,
18 including, but not limited to, copayments and deductibles
19 applicable to these services, and only if these copayments,

1 deductibles, or limitations are disclosed to the subscriber or enrollee
2 pursuant to the disclosure provisions of Section 1363.

3 (2) The department shall expeditiously undertake all steps
4 necessary to implement the fee collection process, including
5 personnel, contracts, and data processing, so as to initiate the fee
6 collection process at the earliest opportunity.

7 (3) The director shall convene, in the most cost-efficient manner
8 and using existing resources, a working group comprised of health
9 insurance, health care service plan, hospital, consumer, and
10 department representatives to evaluate newborn and prenatal
11 screening fee billing procedures, and recommend to the department
12 ways to improve these procedures in order to improve efficiencies
13 and enhance revenue collections for the department and hospitals.
14 In performing its duties, the working group may consider models
15 in other states. The working group shall make its recommendations
16 by March 1, 2005.

17 (4) Effective for services provided on and after July 1, 2002,
18 the department shall charge a fee to the hospital of birth, or, for
19 births not occurring in a hospital, to families of the newborn, for
20 newborn screening and followup services. The hospital of birth
21 and families of newborns born outside the hospital shall make
22 payment in full to the Genetic Disease Testing Fund. The
23 department shall not charge or bill Medi-Cal beneficiaries for
24 services provided under this chapter.

25 (5) (A) The department shall charge ~~a~~ *an additional* fee for
26 prenatal screening to support the pregnancy blood sample storage,
27 testing, and research activities of the Birth Defects Monitoring
28 ~~Program and Biomedical Resources Program activities.~~

29 ~~(6)–~~

30 (B) The ~~initial~~ prenatal screening fee increase for activities of
31 the Birth Defects Monitoring *and Biomedical Resources Program*
32 shall be ten dollars (\$10).

33 ~~(7) The only funds from the Genetic Disease Testing Fund that~~
34 ~~may be used for the purpose of supporting the pregnancy blood~~
35 ~~sample storage, testing, and research activities of the Birth Defects~~
36 ~~Monitoring Program are those prenatal screening fees assessed~~
37 ~~and collected specifically to support those Birth Defects Monitoring~~
38 ~~Program activities.~~

39 (C) *The department shall also charge investigators who are*
40 *approved by the department a fee for costs related to data linkage,*

1 storage, retrieval, processing, data entry, reinventory, and shipping
2 of pregnancy blood or its components and related data
3 management. The funds from fees collected pursuant to this
4 subparagraph may be charged by the department or by an entity
5 authorized by the department to defray or reduce those costs.

6 (D) The funds from fees collected pursuant to this paragraph
7 shall be deposited into the Birth Defects Monitoring and
8 Biomedical Resources Program Fund, which is hereby created as
9 a special fund in the State Treasury, to be continuously
10 appropriated, to carry out the purposes of the Birth Defects
11 Monitoring and Biomedical Resources Program. Notwithstanding
12 Section 16305.7 of the Government Code, interest earned on the
13 moneys in the fund shall also be deposited as revenue into the fund
14 to support the program.

15 (c) (1) The Legislature finds that timely implementation of
16 changes in genetic screening programs and continuous maintenance
17 of quality statewide services requires expeditious regulatory and
18 administrative procedures to obtain the most cost-effective
19 electronic data processing, hardware, software services, testing
20 equipment, and testing and followup services.

21 (2) The expenditure of funds from the Genetic Disease Testing
22 Fund and the Birth Defects Monitoring and Biomedical Resources
23 Program Fund for these purposes related to prenatal and newborn
24 screening shall not be subject to Section 12102 of, and Chapter 2
25 (commencing with Section 10290) of Part 2 of Division 2 of, the
26 Public Contract Code, or to Division 25.2 (commencing with
27 Section 38070). The department shall provide the Department of
28 Finance with documentation that equipment and services have
29 been obtained at the lowest cost consistent with technical
30 requirements for a comprehensive high-quality program.

31 (3) The expenditure of funds from the Genetic Disease Testing
32 Fund for implementation of the Tandem Mass Spectrometry
33 screening for fatty acid oxidation, amino acid, and organic acid
34 disorders, and screening for congenital adrenal hyperplasia may
35 be implemented through the amendment of the Genetic Disease
36 Branch Screening Information System contracts and shall not be
37 subject to Chapter 3 (commencing with Section 12100) of Part 2
38 of Division 2 of the Public Contract Code, Article 4 (commencing
39 with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title

1 2 of the Government Code, and any policies, procedures,
2 regulations or manuals authorized by those laws.

3 (4) The expenditure of funds from the Genetic Disease Testing
4 Fund for the expansion of the Genetic Disease Branch Screening
5 Information System to include cystic fibrosis and biotinidase may
6 be implemented through the amendment of the Genetic Disease
7 Branch Screening Information System contracts, and shall not be
8 subject to Chapter 2 (commencing with Section 10290) or Chapter
9 3 (commencing with Section 12100) of Part 2 of Division 2 of the
10 Public Contract Code, Article 4 (commencing with Section 19130)
11 of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government
12 Code, or Sections 4800 to 5180, inclusive, of the State
13 Administrative Manual as they relate to approval of information
14 technology projects or approval of increases in the duration or
15 costs of information technology projects. This paragraph shall
16 apply to the design, development, and implementation of the
17 expansion, and to the maintenance and operation of the Genetic
18 Disease Branch Screening Information System, including change
19 requests, once the expansion is implemented.

20 (d) (1) The department may adopt emergency regulations to
21 implement and make specific this chapter in accordance with
22 Chapter 3.5 (commencing with Section 11340) of Part 1 of Division
23 3 of Title 2 of the Government Code. For the purposes of the
24 Administrative Procedure Act, the adoption of regulations shall
25 be deemed an emergency and necessary for the immediate
26 preservation of the public peace, health and safety, or general
27 welfare. Notwithstanding Chapter 3.5 (commencing with Section
28 11340) of Part 1 of Division 3 of Title 2 of the Government Code,
29 these emergency regulations shall not be subject to the review and
30 approval of the Office of Administrative Law. Notwithstanding
31 Section 11346.1 and Section 11349.6 of the Government Code,
32 the department shall submit these regulations directly to the
33 Secretary of State for filing. The regulations shall become effective
34 immediately upon filing by the Secretary of State. Regulations
35 shall be subject to public hearing within 120 days of filing with
36 the Secretary of State and shall comply with Sections 11346.8 and
37 11346.9 of the Government Code or shall be repealed.

38 (2) The Office of Administrative Law shall provide for the
39 printing and publication of these regulations in the California Code
40 of Regulations. Notwithstanding Chapter 3.5 (commencing with

1 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
2 Code, the regulations adopted pursuant to this chapter shall not be
3 repealed by the Office of Administrative Law and shall remain in
4 effect until revised or repealed by the department.

5 (3) The Legislature finds and declares that the health and safety
6 of California newborns is in part dependent on an effective and
7 adequately staffed genetic disease program, the cost of which shall
8 be supported by the fees generated by the program.

9 SEC. 2. Section 125002 of the Health and Safety Code is
10 amended to read:

11 125002. (a) In order to align closely related programs and in
12 order to facilitate research into the causes of, and treatment for,
13 birth defects, the Birth Defects Monitoring *and Biomedical*
14 *Resources* Program provided for pursuant to Chapter 1
15 (commencing with Section 103825) of Part 2 of Division 102 shall
16 become part of the Maternal, Child, and Adolescent Health
17 program provided for in Article 1 (commencing with Section
18 123225) of Chapter 1 of Part 2 of Division 106.

19 (b) *The Birth Defects Monitoring and Biomedical Resources*
20 *Program shall develop blood collection and processing protocols,*
21 *determine conditions and duration of blood storage, establish*
22 *exclusion criteria for blood specimens, and institute safe and secure*
23 *methods of disposing of specimens, as determined by the program.*
24 *In addition, the Birth Defects Monitoring and Biomedical*
25 *Resources Program or another entity authorized by the department*
26 *shall store the pregnancy blood for research purposes from all or*
27 *a statistically representative sample population of pregnant women*
28 *who provided a positive consent.*

29 (c) *The department shall analyze the costs of pregnancy blood*
30 *storage and data linkage and management annually, and the*
31 *amount of the fee shall be adjusted by the department to meet the*
32 *costs of the Birth Defects Monitoring and Biomedical Resources*
33 *Program activities.*

34 ~~(b)~~

35 (d) It is the intent of the Legislature that pregnancy blood
36 samples, taken for prenatal screening, shall be stored and used
37 only for the following purposes:

38 (1) Research to identify risk factors for children's and women's
39 diseases.

40 (2) Research to develop and evaluate screening tests.

1 (3) Research to develop and evaluate prevention strategies.

2 (4) Research to develop and evaluate treatments.

3 ~~(e)–~~

4 (e) Before any pregnancy blood samples are released for
5 research purposes, all of the following conditions must be met:

6 (1) Individual consent at the time the sample is drawn to allow
7 confidential use of the sample for research purposes by the
8 department or the department's approved researchers.

9 (2) Protocol review for scientific merit by the department or
10 another entity authorized by the department.

11 (3) Protocol review by the State Committee for the Protection
12 of Human Subjects.

13 ~~(d)–~~

14 (f) When pregnancy blood samples are stored, analyzed or
15 otherwise shared for research purposes with nondepartment staff,
16 no information may be released identifying the person from whom
17 the samples were obtained.

18 ~~(e)–~~

19 (g) Since the pregnancy blood samples described in this section
20 will be stored by the ~~California Birth Defects Monitoring~~ *Birth*
21 *Defects Monitoring and Biomedical Resources* Program or another
22 entity authorized by the State Department of Health Services,
23 Section 103850, pertaining to confidentiality of information, is
24 applicable.